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Supreme Court, U.S.
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No. 04-1047

IN THE

Supreme Court of the United States

WARNER-LAMBERT CO., *et al.*,

Petitioners,

v.

MARY ROSE WAKEFIELD,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE OKLAHOMA COURT OF CIVIL APPEALS

BRIEF IN OPPOSITION

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INTRODUCTION

This is a state court, state law product liability case involving a tragic death caused by Rezulin®. Rezulin was a prescription drug the United States Food and Drug Administration ("FDA") requested be withdrawn from the market after just three years of sales. Michael Wakefield died from Rezulin-induced liver failure, precisely the condition prompting the withdrawal. Michael's widow, Mary Louise Wakefield ("Wakefield"), brought suit against Warner-Lambert Company, its Parke-Davis Division and Pfizer Inc., its successor in interest ("WLC"), the manufacturer of Rezulin. After a three-and-a-half week bifurcated trial, an Oklahoma jury awarded compensatory damages of $1.55 million and punitive damages of $10 million. In unanimously affirming the verdict, the Oklahoma Court of Civil Appeals rejected the plethora of issues WLC raised on appeal. This opinion is unpublished and has no precedential importance. The Oklahoma Supreme Court, likewise acting unanimously, denied WLC's petition for certiorari.

WLC raises only two alleged errors here. First, WLC contends the punitive damage award is excessive and unconstitutional "because it was calculated from world-wide gross sales" in supposed conflict with *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003) and *BMW of North America v. Gore*, 517 U.S. 559 (1996). Petition for Writ of Certiorari ("Pet.") at (i). Second, WLC asserts that the punitive damage award is excessive when compared to the compensatory damage award. *Id.*

WLC's first contention is without merit for the following reasons:

(a) WLC failed to adequately preserve its points of error. WLC's question essentially asks this Court to find one of the following arguments to be correct, yet WLC failed to properly present any of these issues to the Oklahoma Supreme Court in its state Petition for Certiorari (*See Appendix*):

(i) Whether it was unconstitutional or inappropriate for the jury to have considered financial evidence of WLC's Rezulin sales when deciding the appropriate punishment for WLC's intentional and malicious conduct because some of that profit was derived from sales outside of Oklahoma. WLC introduced the very evidence of its worldwide sales of which it now complains. WLC asserts in its Petition to this Court that WLC's financial benefit from Rezulin or "annual gross sales were taken from Warner-Lambert's annual reports" but fails to mention that such annual reports were admitted by WLC itself. Pet. at 7. WLC never redacted any figures on those documents and failed to ask that the documents be admitted for a limited purpose. WLC now argues that the jury should have considered only Oklahoma sales in assessing the appropriate amount of punitive damages to award but WLC never sought to limit its admitted evidence to only Oklahoma sales. WLC should not now be permitted to complain of its own mistakes.

(ii) Whether the jury should have received different jury instructions as to the definitions of certain words contained in the Oklahoma's punitive damage statute or how to properly consider the evidence admitted by WLC regarding its world-wide sales. Before the Oklahoma appellate courts, WLC failed to challenge the jury instructions on punitive damages. Instead, WLC now asks this Court to be the first appellate court to review this issue.

(iii) Whether there was sufficient evidence of WLC's increased financial benefit to justify the punitive damage award. WLC did not raise any issues concerning the sufficiency of the evidence to support the punitive award in its Petition for Certiorari to the Oklahoma Supreme Court and objected to none of the evidence or testimony on this issue. WLC's belated complaints to this Court should fall on deaf ears.

(iv) Whether the Oklahoma punitive damages statute is unconstitutional as it fails to provide adequate definitions for some of the statutory language. WLC never challenged the constitutionality of the statute in its state court Petition for Certiorari on any grounds.

(v) Whether there was sufficient evidence that WLC's worldwide Rezulin sales were gained through illegal conduct. WLC did not preserve this objection (or any of the ramifications of that argument now articulated) in the appellate process.

(vi) Whether WLC had fair notice that worldwide sales could be a basis for a punitive damages award in Oklahoma. WLC never articulated this argument before.

(b) No evidence of unrelated or irrelevant "out-of-state conduct" was introduced, let alone argued, as the basis for a punitive damages award. In the *State Farm* and *BMW* cases, the plaintiffs introduced evidence of misdeeds that occurred outside the plaintiff's home states and affected residents of states outside the plaintiff's home state to prove an alleged pattern of reprehensible conduct. By contrast, each intentional misdeed proven in this case affected Oklahoma residents including Mr. Wakefield (notwithstanding that it affected residents of other states as well). The misconduct here is WLC's intentional, malicious and fraudulent concealment of the harms of Rezulin in its labeling, advertising and other marketing. These are misdeeds that cut across state lines and cannot be deemed to have occurred in any one state as opposed to any other. The evidence at trial was that WLC intentionally concealed important information about Rezulin's liver toxicity from prescribing physicians, including Michael Wakefield's doctor. Because of WLC's false representations, Michael Wakefield was prescribed Rezulin that caused his death. All conduct evidence introduced at trial was directly related to and causative of Wakefield's injury. Further, WLC does not cite this Court to a shred of evidence that it is

legal in any other state to intentionally conceal safety information and deliberately misrepresent a drug's risks in order to induce sales.

"Out-of-state sales" are distinct from "out-of-state misconduct." *State Farm* and *BMW* stand for the proposition that a defendant should not be punished for particular acts of misconduct that occurred in other states. WLC asks this Court to confuse sales data or financial information appropriate for determining the appropriate amount for a punitive damage award with judgment by a jury of a company's out-of-state conduct. These are two wholly separate concerns. The act of factoring overall profitability into a punitive damages award simply seeks to make the punishment commensurate with the wrongdoer's wealth. Under WLC's contorted reasoning, if a pharmaceutical company deliberately misrepresented a drug in a nationwide advertising campaign but only sold one pill of that drug in a certain state causing death to the state resident, that state has no power to punish that defendant for its intentional and malicious acts which caused a resident's death beyond the earnings for that one pill. This argument asks the Court to remove a jury's ability to consider net worth or sales data in order to set a punitive award that would be sufficient to deter similar future conduct in that state.

(c) WLC offers no evidence suggesting the evidence of worldwide sales factored into the jury's consideration, let alone that it was likely dispositive to the jury's decision. The jury was clearly permitted under the Oklahoma punitive damages statute to consider WLC's net worth or financial condition when assessing the amount of punitive damages necessary to punish WLC for its intentional and malicious conduct. WLC now asks this Court to speculate that the jury also used this financial information to punish WLC for lawful out-of-state conduct. As the Oklahoma Court of Civil Appeals has already told WLC, its "argument is nothing more than

conjecture about the basis for the jury's specific punitive damages award. The Manufacturing Defendants demonstrate no facts to overcome the presumption the jury followed its instructions and determined punitive damages accordingly." COCA Opinion Pet. App. at 17.

Moreover, WLC's second presented question is not worthy of review because the punitive damage award is not disproportionate to the compensatory damage award. This is especially true since the punitive damage award is for misconduct that caused incapacitating death rather than mere economic damage such as the need for automobile repair.

In light of the significant waiver issues present in this case, it is a uniquely poor candidate for certiorari. WLC disguises what is nothing more than a challenge to the sufficiency of the evidence, the admissibility of its own evidence or the adequacy of the trial court's jury instructions (arguments which were not preserved) into a constitutional argument. WLC does not even claim that there is a division of authority among the lower courts but merely asserts that the punitive damage award is in conflict with this Court's *State Farm* and *BMW* precedent. WLC asks this Court to now expand those holdings to exclude not just punishment by a state for irrelevant and unrelated out-of-state conduct but also to prohibit consideration by a jury of relevant and material financial or net worth evidence (which in this case was introduced by WLC itself).

COUNTER STATEMENT OF THE CASE

The questions raised in WLC's petition for certiorari relate solely to the ***amount*** of the punitive damages awarded. WLC never argues that Wakefield is not entitled to punitive damages and does not contest that WLC's conduct was intentional and malicious. However, WLC includes pages of what is essentially jury argument on factual and evidentiary issues in its Petition to the Court. Wakefield will thus first respond to those assertions

even though most of them have little or no bearing on the two questions presented.

Background – General Liability Evidence. Rezulin was on the market only three short years before WLC agreed to the FDA's request that it be removed because of the drug's excessive liver risks. No other oral diabetic medication on the market causes a similar level, severity or frequency of liver injuries. No other diabetic medication has been removed from the market because of its toxicity.

At trial, the jury heard evidence on more than two dozen examples of WLC's "deliberate false statements, acts of affirmative misconduct and concealment of evidence of improper motive." *BMW*, 517 U.S. at 560. On a number of occasions, WLC specifically misrepresented the liver toxicity of Rezulin, intentionally concealed data from its Rezulin studies and affirmatively misled physicians about the drug's risks. The jury found by clear and convincing evidence that WLC acted "intentionally and with malice towards others." WLC does not challenge the jury's findings on these points.

Lawsuits were filed both while Rezulin was on the market and after its withdrawal. In several trials, juries strongly condemned WLC's conduct concerning Rezulin and found WLC's wrongdoing to be intentional and malicious. Now, however, the litigation is virtually over. WLC has settled the vast majority of the pending Rezulin cases and paid compensation to tens of thousands of injured people. There are no other appeals pending. Only a small fraction of the cases still remain for resolution.

The bulk of the Wakefield's general liability and causation evidence came from Dr. John Gueriguian ("Gueriguian"). Gueriguian, a former FDA medical officer, had worked on the approvals of more than one hundred drugs including every

diabetic medication on the market in America before 1996. R. 3785, Tr. 391-92, 406. From 1989 to 1996, Gueriguian was the actual medical officer assigned to the drug Rezulin and had factual experience working with WLC and this drug. R. 3785, Tr. 392, 444; R. 3827, PX-1259. Gueriguian is a medical doctor and a former professor of pharmacology. He completed a fellowship at Harvard University in endocrinology and has specialized medical training in internal medicine, biochemistry and chemistry. R. 3785, Tr. 296, 395-403. Because of his education, experience and personal involvement with Rezulin he was specifically qualified to offer his opinions. A cursory review of Gueriguian's trial testimony reveals the extent of WLC's deceit and unconscionable conduct in this case.

WLC purposefully concealed the signals of Rezulin's liver toxicity uncovered in the drug development process, marketed Rezulin as a drug with "side effects comparable to placebo" and then consistently assured physicians that Rezulin had an excellent safety profile, presenting little risk to patients. R. 3788, Tr. 765-66. WLC knew that the reality was the exact opposite. Gueriguian painstakingly educated the jury about the steps taken by drug companies to develop a new drug and WLC's decision to conceal the information learned through such testing. R. 3786, Tr. 435-39. At each of these steps (cell testing, animal testing and human studies), Rezulin showed a clear signal of liver and blood toxicity. Instead of acting responsibly and halting development (like two other companies did with similar compounds), WLC forged ahead to rush Rezulin to market in order to capitalize on the "first to market" profits and chose to conceal these results from the prescribing physicians. R. 3789, Tr. 910-16; R. 3787, Tr. 660-61; R. 3786, Tr. 457-59, 462-65; R. 3827, PX-2517, 2613, 3623.

Pre-approval cell testing showed that Rezulin-treated cells died quickly and in an unpredictable manner – a "highly unusual" finding. R. 3786, Tr. 465-69; R. 3827, PX-4058. Further cell

testing confirmed that Rezulin was liver toxic even at low concentrations. R. 3786, Tr. 469, 485-508; R. 3827, PX-1594. Cell testing done before the drug was even approved showed an alarming range and severity of liver toxicity. R. 3812, Tr. 2526-55. WLC deliberately hid these results from the doctors throughout the time that the drug was being sold and published these findings only after removing Rezulin from the market. *Id.*

Animal studies showed that Rezulin was liver toxic in every animal species tested. R. 3786, Tr. 509, 511; R. 3827, PX-429, 439, 441, 917, 2726. These liver effects showed up at concentrations even below anticipated human doses – a finding that was "very unique" and not seen by Gueriguian in his "20 years at the FDA for any other drug." R. 3786, Tr. 521. Both Gueriguian and WLC's own FDA expert, Dr. Garvey, admitted that the animal studies signaled Rezulin's liver injury potential. R. 3787, Tr. 564; R. 3804, Tr 1998. WLC again chose never to warn doctors about these findings and deliberately never conducted human studies to better understand the drug's liver toxicity potential. R. 3787, Tr. 660-61; R. 3827, PX-165; R. 3804, Tr. 2001.

Although the human testing further confirmed Rezulin's liver toxicity, WLC systematically misrepresented this data. For example, when WLC's human studies showed that fifty-six (56) volunteers had suffered liver injury, WLC chose to report that there were only fourteen (14) patients with abnormal liver enzyme ("ALT") levels. R. 3788, Tr. 720; R. 3788, Tr. 726-27; R. 3827, PX-2524. This is a serious violation of a drug company's duty to report its study results accurately. Dr. Garvey, WLC's own FDA expert, testified that for a drug company to make this type of incorrect representations about clinical trial data "would be criminal." R. 3804, Tr. 2001-02.

1. WLC repeatedly altered the results of its human studies and concealed such data from physicians. R. 3786, Tr. 532-33; R. 3827, PX-127, 128, 133, 1281, 3660. One important example involved Dr. Janet McGill ("McGill") and the Rezulin "042" study. McGill was WLC's principal investigator at one of the five sites set up for this human study. She later came forward and reported to the FDA and Congress that WLC had falsified the data from her trial site. R. 3787, Tr. 686-88. WLC's final study report on the 042 trial stated that there were no liver abnormalities seen in the entire study (which included five testing sites). R. 3787, Tr. 678-79; R. 3827, PX-744. In reality, there were four patients with elevated ALT levels at McGill's site alone. R. 3787, Tr. 678-85. McGill further revealed that WLC had coerced her to change how she defined the adverse events she observed as well as her causation assessments regarding the relationship between Rezulin and those events. R. 3788, Tr. 700-01; R. 3787, Tr. 686-88; R. 3827, PX-735.

2. WLC concealed clinical trial deaths. Human study data is awarded great importance because the patient volunteers are more carefully monitored and evaluated than the general population to protect them from injury. Despite these precautions, three volunteers in the Rezulin human studies died from liver injuries. R. 3788, Tr. 840-70. The first of these deaths occurred in May 1998 in a study conducted by the National Institute of Health ("NIH"). R. 3788, Tr. 831-33. Both WLC's liver expert and the NIH's panel of three esteemed liver specialists concluded that Rezulin caused the patient's liver injury. R. 3788, Tr. 835-40. This was an important finding because this volunteer had two separate medical problems occurring simultaneously (like Wakefield) and it was the patient's liver dysfunction that limited her ability to combat the other issue, ultimately leading to her death (again, like Wakefield). R. 3814, Tr. 2826-28; R. 3827, PX 671. Instead of revealing these findings, WLC issued a statement to the public and prescribing physicians contradicting the experts' opinions and expressly stating that the patient died

"due to complications unrelated to the study or the medication." R. 3789, Tr. 842; R. 3827, PX 2049. Further, WLC never included information or warnings about any of these clinical trial deaths in the Rezulin label. R. 3789, Tr. 915.

3. WLC consistently misrepresented and understated Rezulin's risk statistics. While WLC's own statistics (based upon the clinical trial deaths alone) showed that Rezulin's risk of a fatal liver event was 1 in 5,800, WLC never warned doctors about this risk level. R. 3789, Tr. 875; R. 3827, PX-3196. Instead, the company reassured doctors by misrepresenting that the risk of liver transplantation or death from Rezulin was rare and in the order of 1 in 60,000. R. 3789, Tr. 894; R. 3827, PX 227.

4. Rezulin warnings were deliberately inaccurate. For example, the label reassured doctors that there were only forty-eight (48) patients with elevated ALTs in the human studies. R. 3827, PX-165. WLC knew that there were actually eighty-eight (88) such patients but chose to hide that data. R. 3788, Tr. 730-32; R. 3827, PX-3663; R. 3788, Tr. 735-36; R. 3789, Tr. 854; R. 3793, Tr. 1417. Second, the label represented that there were only two cases of jaundice seen in the clinical trials, but WLC's corporate representative, Dr. Robert Zerbe, admitted this representation was "wrong" and not a "correct statement." R. 3814, Tr. 2820-23. Third, WLC represented that Rezulin liver injuries were "rare" even though trial evidence confirmed that this description was "highly inappropriate" since the accurate statistics were as high as one serious liver injury in every three hundred (300) people. R. 3789, Tr. 908-11.

5. Financial motive. The jury also heard evidence about WLC's financial motive. In 1996, WLC was in deep financial trouble: its stock price was low, sales were flat, the company had poor profitability, an important patent had expired (exposing WLC to generic competition), and WLC had experienced

research and development failures. Manufacturing problems led to a consent decree that cost WLC a $1 billion loss in sales. R. 3806, Tr. 2183-89; R. 3814, Tr. 2760-61; R. 3827, PX-1401. WLC's hope for financial rescue was Rezulin: a "project born of necessity, a sense of urgency created by the need for sheer survival." R. 3827, PX-1415. WLC was under grave financial pressure to bring Rezulin to market with as few warnings as possible in order to maximize its sales potential. WLC intentionally concealed the drug's liver toxicity from physicians and patients to induce tremendous sales. WLC's stock soared and the drug earned more than $2 billion. R. 3806, Tr. 2156-59, 2100-01.

6. Efficacy. WLC knew that Rezulin had lower efficacy and higher risks in relation to the other oral diabetic drugs available at the same time. R. 3788, Tr. 738-41; R. 3789, Tr. 913-14. Yet WLC's Petition cites repeatedly to unsubstantiated anecdotal or observational comments about Rezulin's efficacy while refusing to address the scientific statistical evidence presented at trial that the other two classes of diabetic medications available had significantly greater efficacy. *Id.*

Efficacy as measured by:	***Rezulin***	***Metformin/ Glucophage***	***Sulfonylureas***
Percentage reduction in blood sugar levels (HbA1C)	**1.2 – 1.5%**	**1.8% - 2.2%**	**1.8 – 2.2%**

Background – Michael Wakefield. Wakefield died in the prime of his life, at age 42. He was a high wage earner, making $24,000 a month at the time of this death. R. 3801, Tr. 1937. Expert testimony at trial established that loss of wages alone resulted in his estate suffering economic damages of more than $5 million. R. 3801, Tr. 1952.

Michael Wakefield died in intensive care. As his liver injury escalated, the ammonia levels in his brain built up, causing confusion. Eventually, the doctors were forced to tie him to his hospital bed. R. 3808, Tr. 2249. He turned yellow from jaundice. On the morning of his death, the doctors discussed a liver transplant with his family. However, Wakefield died before that surgery could be performed. R. 3808, Tr. 2252.

Substantial evidence revealed that Rezulin proximately caused Wakefield's death. The Oklahoma Court of Civil Appeals found that Plaintiff's expert, Dr. Neil Julie's ("Julie") expertise, experience and training made him highly qualified to offer causation opinions concerning Rezulin-induced injuries. Julie received his medical degree from Cornell University, earning double board certification in internal medicine and gastroenterology. R. 3794, Tr. 1522. He is experienced in toxic exposure causation assessments. R. 3794, Tr. 1523. In addition to treating patients in his medical practice, Julie is also a consultant, a clinical researcher for pharmaceutical companies, and devotes a substantial part of his practice to the study of liver diseases. R. 3794, Tr. 1526. Julie published the first medical article on Rezulin-induced liver toxicity. Before becoming involved in the Rezulin litigation, Julie diagnosed and treated three patients with Rezulin-induced liver damage. R. 3794, Tr. 1527. Case reports on two of these patients were published in the prestigious medical journals *Annals of Internal Medicine* and *American Journal of Gastroenterology*. R. 3794, Tr. 1527-31; R. 3795, Tr. 1568, 1577.

Both Julie and WLC's expert (Dr. Joel Greenson) agreed that Wakefield's condition involved multiple factors uniquely characteristic of a Rezulin liver injury. R. 3827, PX-2241. Wakefield had ALT levels in his blood that were more than four times normal limits. Not surprisingly, he developed jaundice. R. 3795, Tr. 1601-03. Pathology showed degenerative liver changes, necrosis (liver cell death), active hepatitis (liver

inflammation), a lack of zonal pattern to the necrosis and eosinophils (a finding unique to Rezulin injuries). R. 3795, Tr. 1601-04; R. 3804, Tr. 2049-50; R. 3810, Tr. 2354-59; R. 3827, PX-2241. Wakefield's autopsy showed prominent cholestasis, a condition commonly seen in Rezulin-induced liver injuries. R. 3795, Tr. 1576, 1605.

WLC argues here (as though it is asking this Court to become a second jury) that Wakefield died from hemolytic anemia caused by another drug, Rocephin. However, the medical records showed that the hemolysis blood disorder started *before* Wakefield ever received Rocephin and thus could not have been caused by Rocephin. R. 3795, Tr. 1596-98. While Julie testified during cross-examination that Rezulin can cause hemolytic blood disorders like that suffered by Wakefield, he concluded that issue was irrelevant because Wakefield's liver disorder was caused by Rezulin. R. 3795, Tr. 1610-11. Julie further testified that Wakefield would not have died *but for* his Rezulin-induced liver dysfunction, no matter what the cause of the blood hemolysis. R. 3795, Tr. 1610-11.

Procedural Background. Mary Rose Wakefield filed a wrongful death lawsuit against WLC in October of 2000 asserting claims under theories of product liability, negligence and intentional misrepresentation and fraud. Wakefield originally also sued the decedent's prescribing physician but dismissed him before jury selection. WLC then removed the case to federal court on the first day of trial in an attempt to avoid the long-confirmed trial setting. The federal district court ruled within hours of such removal that there was no fraudulent joinder of the physician or "ploy to defeat diversity" and remanded the case by the end of the day.[1]

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1. In his Order of Remand, Judge Ellison rejected Warner-Lambert's arguments for removal since he was, "not convinced by the facts recited by Defendants that the suit against [defendant] Dr.

(Cont'd)

The jury found in favor of the plaintiff, awarded compensatory damages and further held that WLC had acted intentionally and maliciously. During a separate punitive damages phase, the jury was instructed that it could award punitive damages "for the sake of example and by way of punishing the defendant" based on seven factors.[2] After further deliberation, the jury returned a punitive damages award of ten million dollars ($10,000,000).

WLC filed post-verdict briefing which raised forty-four (44) individual points of error, challenging the admission of evidence, the sufficiency of the evidence to support the jury's verdicts as well as various procedural arguments. R. 3294-3464. The trial court denied WLC's requested post-trial relief. On appeal, WLC abandoned many previously claimed points of error and focused its appeal on the admission of one expert's testimony, two jury instructions, the admission of the corporation's felony conviction and a challenge to the punitive damages award.[3] As for the punitive award, WLC devoted only three-and-a-half pages to five specific challenges.

(Cont'd)

Levit was in bad faith, or was intended solely to defeat removal, or even that Plaintiffs never intended to pursue the suit against Dr. Levit to its completion. In this regard, the Court gives great weight to Defendant's admission that they are not arguing that there was no factual basis for the claim against Dr. Levit. With this admission, Defendants effectively concede that Dr. Levit was not fraudulently joined in order to defeat jurisdiction."

2. (1) Seriousness of the hazard to the public arising from the defendant's misconduct; (2) the profitability of the misconduct to the defendant; (3) the duration of the misconduct and any concealment of it; (4) the degree of the defendant's awareness of the hazard and its excessiveness; (5) the attitude and conduct of the defendant upon the discovery of the misconduct or hazard; (6) the number and levels of corporate employees involved in causing or concealing the misconduct; and (7) the financial condition of the defendant. OKLA. STAT. TITLE 23 § 9.1A

3. Under Oklahoma law, all appeals are filed with the Oklahoma Supreme Court which either hears the appeal itself or refers it to the

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As to the punitive damages award, the Oklahoma Court of Civil Appeals found that "the jury was correctly instructed according to the strict terms of 23 O.S. Supp. Paragraph 9.1." Pet. App. 14. Second, the Oklahoma Court of Civil Appeals disagreed with WLC's challenge to the sufficiency of the evidence to support the punitive award. The Oklahoma Court of Civil Appeals actually cited to just a fraction of the financial evidence introduced at trial to demonstrate that "this testimony, along with that establishing the gross sales of the drug, clearly provided a basis for jury determination of increased benefit to Manufacturing Defendants." Pet. App. at 17. In conclusion, the court found adequate "evidentiary support for the award of punitive damages." *Id.*

The court then addressed WLC's arguments under *State Farm* that there was an "insufficient nexus between the punitive damages and the actual harm suffered by plaintiff." Pet. App. at 17. The Oklahoma Court of Civil Appeals again rejected this contention because "the jury was specifically instructed regarding the basis for awarding punitive damages and absent proof to the contrary, it is presumed that the jury followed its instructions." *Id.* The court further found that WLC's argument was "nothing more than conjecture" since WLC "demonstrate no facts to overcome the presumption the jury followed its instructions and determined punitive damages accordingly." *Id.*

Finally, the court addressed WLC's argument that the award violated the guidelines outlined in *BMW*. After setting forth the principles of *BMW*, the court concluded that:

> Manufacturing Defendants do not specifically elucidate how the result of this case violates either of these principles, and we find it does not. The punitive damages award in this case neither reflects a

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(Cont'd)
Oklahoma Court of Civil Appeals for disposition (as the Oklahoma Supreme Court did here). A petition for writ of certiorari may then be filed with Oklahoma Supreme Court.

> grossly excessive award nor attempts to sanction Manufacturing Defendants for conduct legal in other states. We find no merit to this contention of error.

Pet. App. at 18

In WLC's Petition for Certiorari to the Oklahoma Supreme Court, WLC narrowed its points of error on the punitive damages issue even further. WLC devoted less than two and one-half pages of its Petition to challenges to the punitive damages award and severely restricted its objections. *See Appendix*. WLC failed to preserve many of the issues now raised before this Court.

REASONS FOR DENYING THE PETITION

I. WLC Has Failed To Demonstrate That Its Federal Claims Were Properly Presented To The Oklahoma Courts.

Under "well settled" doctrine animated by federalism concerns, this Court does not review the final judgments of state courts unless "'the record as a whole shows either expressly or by clear implication that the federal claim was adequately presented in the state system.'" *Board of Dir. of Rotary Int'l v. Rotary Club of Duarte*, 481 U.S. 537, 549-50 (1987) (citation omitted). Where a state supreme court's opinion is silent on a federal issue, this Court properly assumes that the issue was not properly presented and will not grant a writ of certiorari unless the petitioner demonstrates that the state court had "'a fair opportunity to address the federal question that is sought to be presented.'" *Adams v. Robertson*, 520 U.S. 83, 86-87 (1997) (per curiam) (citation omitted) (dismissing writ of certiorari as improvidently granted). To confirm that an issue was fairly presented to the state courts, this Court requires the petitioner to establish that the claim was "raised at the time and in the manner required by state law," and that the claim was presented "with fair precision and in due time." *Id.*

WLC has not and cannot show that it raised its claims in the manner required. WLC identified a number of points of error regarding punitive damages in its post-trial briefing but by the time WLC filed its Petition for Certiorari with the Oklahoma Supreme Court, WLC made a tactical decision to significantly narrow its punitive award issues. All points of error not raised in the petition for error are deemed waived under Oklahoma procedural rules. *Peters v. Golden Oil Co.*, 600 P.2d 330 (Okla. 1979) ("Assignments of error which are not argued or supported in brief with citations of authority will be considered and treated as waived by this Court")[4]; *Johnson v. Ford Motor Co.*, 45 P.3d 86, 89 (Okla. 2002) (Each allegation of error not contained within argument in brief is waived). Moreover, "naked argument unsupported by facts or authority is without merit and will be treated as waived." *Tiger Flats v. Oklahoma Petroleum*, 711 P.2d 106, 108 (Okla. 1985).

A. WLC Waived Its Complaint About the Admission of Worldwide Sales Evidence Because WLC, Itself, Introduced Such Evidence.

Since WLC was the party who sought admission of the annual reports and shareholder statements containing the world-wide sales information, WLC cannot now complain that such evidence was inappropriate. *Ohler v. United States*, 529 U.S. 753, 756 (2000) ("a party introducing evidence cannot complain on appeal that the evidence was erroneously admitted"). Indeed, when WLC moved to admit these documents, it failed to seek redaction or admission for a limited purpose and cannot now complain of its own evidence. R. 3806, Tr. 2147-53.

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4. *See also* Okla. Sup. Ct. Rule 1.11(f): "The main contentions of the parties must be set forth in separate propositions. The argument and authorities in support of each proposition must follow the statement of the proposition . . ."

B. WLC Waived Its Objections to Jury Instructions by Not Raising Them in the Appellate Courts Below.

The essence of WLC's claims before this Court is that the jury received inappropriate or inadequate jury instructions during the punitive damage phase. The trial court instructed the jury according to the Oklahoma statute both as to the amount of damages that could be awarded and the factors that the jury could consider in awarding damages. For the first time before this Court, WLC now claims that the trial court committed numerous errors related to the punitive damages jury instructions including that the trial court "gave the jury a perfunctory instruction" and failed to give the jury any limitations (other than the Oklahoma Uniform Jury Instruction) on how it could calculate and award punitive damages. WLC further complains the trial court failed to properly define various statutory phrases including the "other persons or entities" language, for whom the financial benefit from harm could be calculated, or the geographic location of such other persons or entities. Pet. at 6.

WLC asserts that it requested certain jury instructions at the time of trial related to the punitive damages instructions. Pet. at 6. However, on appeal, WLC never presented any claim of error as to the punitive damage jury instructions to the Oklahoma courts below. Since WLC's challenges relate to definitions of phrases from the Oklahoma statute, it was incumbent upon WLC to present all arguments regarding the punitive damages instructions to the Oklahoma courts. Under Oklahoma procedural rules, any and all errors relating to jury instructions on punitive damages were waived by the failure to present the issue to the Courts of Oklahoma. Oklahoma Supreme Court Rule 15 requires a party complaining of an instruction given or refused to set out *in totidem verbis* the instruction or the portion thereof to which he objects together with his objection thereto. All "errors in refusing requested instructions or in giving

objectionable instructions are waived when not set out in compliance with this rule." *Avard v. Leming*, 889 P.2d 262, 266 (Okla. 1995). Indeed, the Oklahoma Supreme Court has stated that "Rule 15 contains no exceptions to its requirements . . ." *Ibid. See Howell v. Mississippi*, 125 S. Ct. 856 (2005) (*per curiam*) (writ dismissed as improvidently granted where petitioner failed to show that federal claim involving jury instruction was properly presented to state supreme court). In the instant case, WLC did not comply with Rule 15, and never allowed the Oklahoma courts to consider these potential points of error but now want this Court to be an appellate court of first review.

C. WLC Failed to Preserve Error on Its Challenges to the *BMW* and *State Farm* Factors.

To the extent WLC referred at all to *BMW* or *State Farm* in its initial Brief in Chief, it did so only in ***three*** sentences. That can hardly be sufficient to apprise the state courts of the nature of WLC's federal claims. This Court has previously held that "the discussion of a federal case in the midst of an unrelated argument, is insufficient to inform a state court that it has been presented with a claim." *Adams v. Robertson*, 520 U.S. 83, 88 (1997). Moreover, a ***three*** sentence argument would be insufficient to preserve any alleged error under Oklahoma procedural rules. *Oklahoma City Urban Renewal Authority v. City of Oklahoma City*, __ P.3d __, [Vol. #] WL 44399 (Okla. 2005) ("naked argument unsupported by facts or authority is without merit and will be treated as waived.") *quoting Tiger Flats v. Oklahoma Petroleum*, 711 P.2d 106, 108 (Okla. 1985). The Oklahoma Court of Civil Appeals expressed its frustration with WLC's obvious attempt at sandbagging by noting that that WLC failed to "specifically elucidate" how this case violated the principles of *BMW*.[5] In an abundance of caution, the

5. As discussed *supra*, WLC never made a challenge to the punitive damage award under of any of the *BMW v. Gore* "guideposts" in the courts below.

Court of Civil Appeals analyzed the award itself under all possible objections that WLC could have detailed (but chose not to) and stated that it did not find the punitive damage award grossly excessive under *BMW*. Pet. App. at 17.

D. WLC Waived Its Challenges to the Constitutionality of the Oklahoma Punitive Damages Statute.

In its state Petition for Certiorari, WLC failed to challenge the Oklahoma punitive damage statute as unconstitutional or specifically articulate the trial court's error and relied only upon broad policy arguments. *See Appendix.* All courts recognize a litigant's obligation to spell out its arguments "squarely and distinctly." *United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990) ("It is not enough merely to mention a possible argument in the most skeletal way, leaving the court to do counsel's work, create the ossature for the argument, and put flesh on its bones"). *See also Hardeman v. City of Albuquerque*, 377 F.3d 1106, 1122 (10th Cir. 2004) ("issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

For the first time before this Court WLC argues that the punitive damage statute 23 O.S. § 9.1 is unconstitutional because "on its face, the statute fails to provide juries and courts with standards sufficient to constrain them from making awards calculated on the basis of out-of state transactions." Pet. at 16. Nor did WLC preserve error regarding the court's jury instructions on this issue. Here WLC asks this Court to revisit the constitutional issues addressed in *BMW* and *State Farm*, even though such constitutional challenges were not fully and fairly presented to the courts below. Had WLC provided any substance at all to its constitutional argument, the Oklahoma courts could have addressed WLC's specific and detailed objections. WLC cannot sneak through the back door what it failed to present to state courts through the front.

II. The Opinion Below Withstands Scrutiny Under Both The *BMW* And The *State Farm* Analysis.

This Court explained in *BMW* and *State Farm* that the Fourteenth Amendment's Due Process Clause forbids the imposition of "grossly excessive" punitive damages by state courts. Courts reviewing punitive damages awards must therefore not only assess the nature and strength of state interests in deterring the conduct at issue, but also the proportionality of the damages in comparison to (1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages awarded; and (3) the difference between the punitive damages awarded and civil or criminal sanctions authorized or imposed in comparable cases. *State Farm*, 538 U.S. at 418; *BMW*, 538 U.S. at 568, 575.

WLC assails the Court of Civil Appeal's "perfunctory appellate decision" regarding the punitive damages issues and contends that the lower courts failed to analyze this case in light of the principles this Court established in *BMW* and *State Farm*. Pet. at 17. In truth, it was WLC that failed to adequately present or articulate its constitutional challenges to the courts below. The thrust of WLC's challenge to the punitive damage award was made on state law grounds. When the issue is properly raised, the Oklahoma Supreme Court has remitted punitive damages awards under the principles of *BMW*. *See Frank v. Mayberry*, 985 P.2d 773, 777 (Okla. 1999) ($200,000 damage award reduced to $50,000 in light of actual damage award of only $300). Importantly, this case was not even cited by the defendants in any of its briefing to the courts below.

Nevertheless, as outlined below, this punitive damage award is consistent with the principles of *BMW* and *State Farm*. Punitive damages may properly be imposed to further a State's legitimate interests in punishing unlawful conduct and deterring its repetition.

BMW, 517 U.S. at 568. Oklahoma has put in place a thoughtful, strict and appropriate statute to fulfill such interest and the jury in this case carefully applied it.

A. The Evidence of Increased Financial Benefit to WLC Justifies the Award.

WLC reasserts the argument made to the Oklahoma Court of Civil Appeals that there was a lack of evidence to support what financial benefit was derived by WLC from its wrongful conduct concerning Rezulin. The Oklahoma Court of Civil Appeals rejected this argument based upon its review of the actual evidence admitted at trial. WLC chose to not ask the Oklahoma Supreme Court to review that decision but now wants this Court to consider this argument anew.

Because Rezulin was first in its class, WLC was able to price the drug even higher than what was necessary to make a reasonable profit on the drug. In fact, WLC's Pricing Committee recommended a price for the drug that would have permitted a comfortable profit. R. 3806, Tr. 2093-94. Instead, senior management elected to market the drug at an even higher price than recommended by the Pricing Committee in order to further increase the company's profit margin. *Id.* So while other WLC drugs carried a profit margin of 15%, Rezulin's profit margin, as confirmed by the company's own internal documents, was as 31.7% for the year 1999. R. 3806, Tr. 2090-93; R. 3827, PX-1401, 2946. WLC documents also confirmed ***net*** Rezulin sales per month of $48 million. R. 3806, Tr. 2104; R. 3827, PX-2286. WLC states in its Petition that "there was no evidence of actual profits" even though Plaintiffs' exhibits 2946 and 2286 are WLC's own documents containing this exact evidence.

In the punitive damages phase, Wakefield's counsel referenced the annual shareholder reports introduced into evidence by WLC when discussing the increased financial benefit

to WLC. These documents, which included worldwide sales figures, coupled with the evidence discussed above, provided the jury with information that WLC's profits from Rezulin were over $600 million. WLC sold very little Rezulin outside of the United States of America because it only had the right to sell the drug in a handful of other countries (where the drug was approved for very limited use) resulting in miniscule sales. R. 3786, Tr. 440; R. 3793, Tr. 1407. Further, WLC's own expert testified that Oklahoma has the largest percentage number of diabetics of any other state in the country with close to 20% of the Oklahoma residents being susceptible to the disease. R. 3817, Tr. 3003. Just using simple math, with $600 million in profits, the jury had evidence before it that the Oklahoma sales alone exceeded $10 million. Due to the wide use of Rezulin in Oklahoma in light of that state's prevalence of diabetes, the jury could have inferred from the evidence at trial that a disproportionate share of Rezulin sales likely occurred in Oklahoma making such sales far in excess of $10 million.

B. The Jury Did Not Punish WLC for Otherwise Lawful Conduct.

Intentionally misrepresenting the risks and benefits of a prescription drug that then causes injury and death in order to induce sales is not legal in any state – a very different scenario from the *BMW* facts. Even WLC does not argue that the conduct assessed by this jury would be lawful in any other state. The Oklahoma Court of Civil Appeals correctly stated that the award in this case does not attempt "to sanction for conduct legal in other states." Pet. App. 18.

Further, the clear evidence at trial was that WLC's nationwide wrongful conduct including fraud and concealment of Rezulin's significant liver toxicity lead to the specific representations made to (and relied upon by) Oklahoma resident Michael Wakefield and his prescribing physician. The jury found

these representations to be intentionally fraudulent. Based upon WLC's false assurances of the drug's safety, Michael Wakefield was prescribed Rezulin which caused his death. All evidence of WLC's wrongdoing admitted at this trial was directly related to Michael Wakefield injury and death. *State Farm*, 538 U.S. at 1519. Unlike the *BMW* case, all of the admitted evidence had a direct impact on Oklahoma and its residents, including Michael Wakefield. *BMW*, 517 U.S. at 1597. WLC was punished by this jury for its intentional conduct that directly led to Michael Wakefield's death in Oklahoma. *State Farm*, 538 U.S. at 1521. The fact that precisely the same acts may have resulted in deaths in other states as well is irrelevant. WLC now asks this Court to significantly expand the Court's reasoning in *State Farm* and *BMW* to hold that because WLC itself introduced evidence at trial that showed its net worth, financial condition and worldwide sales, the punitive damage verdict is inappropriate and unconstitutional. R. 3826, DX 8001, 8002, 8003.

C. The Oklahoma Punitive Damages Award Statute Is Constitutional.

"A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction." *State Farm*, 538 U.S. at 1523. Oklahoma did exactly this when it enacted 23 O.S. Supp. 2003 § 9.1. The statute provides clear and strict guidance to the trial courts as to how to instruct jurors on all factors that they may consider when awarding punitive damages. A jury may consider, *inter alia*, financial condition or net worth in order to assess an appropriate amount of punitive damages to set an example or punish a defendant. 23 O.S. Supp. 2003 § 9.1 (A) (7). To provide further protection against "multiple punitive damages awards for the same conduct," the statute requires a trial court to reduce any punitive damage award if the defendant has already paid

other punitive damage verdicts in the state of Oklahoma for the same conduct. *State Farm*, 538 U.S. at 1523; 23 O.S. Supp. 2003 § 9.1 (C) (2).

As explained above, the evidence in this trial did not relate to irrelevant "out-of-state misconduct." WLC's bad acts cut across state lines but came home to roost in Oklahoma. Moreover, considering global sales is wholly distinct from considering wrongful acts in other states. Whereas the former focuses on the impact of the award, the latter focuses on the particular acts being punished.

Finally, the trial court correctly instructed the jury on each factor to be considered in this award. There is no evidence to suggest the jury awarded damages based on any single factor – or piece of evidence – over any other. There is **NO** evidence in the record that the jury considered WLC's worldwide Rezulin sales for any inappropriate purpose – and WLC provides no proof or evidence of such. WLC does not cite to any evidence or argument of counsel that inappropriately asked the jury to consider dissimilar or unrelated lawful out-of-state conduct and punish WLC for such conduct through its punitive damage award. This is because no such evidence or argument exists. Rather the trial court limited the evidence to documents and testimony that related to the design and warnings of this drug as related to Michael Wakefield's use of Rezulin. Now, WLC asks this court to speculate that the jury ignored the court's instructions on the specific factors to consider when awarding punitive damages and instead used the documents introduced by WLC itself to inappropriately punish WLC for out-of-state conduct that was unrelated to the facts of this case. The Oklahoma Court of Civil Appeals summarily rejected this very same argument by WLC.

D. WLC Had Fair Notice of the Scope of Punitive Damage Exposure Because of Possible Civil or Criminal Penalties.

A company is entitled to "fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose." *State Farm*, 538 U.S. at 1520. States have "considerable flexibility in determining the level of punitive damages that they will allow." *BMW*, 517 U.S. at 568. One factor that assists in the concept of fair notice is the civil or criminal penalties "that could be imposed for comparable misconduct." *BMW*, 517 U.S. at 583; *State Farm*, 538 U.S. at 1526. Corporations doing business in Oklahoma have fair notice of Oklahoma's possible penalties from the punitive damages statute itself which permits punishment up to the "increased financial benefit" derived from intentional, wrongful and malicious conduct. 23 O.S. Supp. 2003 § 9.1(C)(2)(c). Additionally under 78 OKLA. STAT. § 54, the attorney general, on behalf of Oklahoma consumers, can divest a corporation of all money received by a wrongdoer who engages in deceptive acts in Oklahoma. Deceptive acts include, "knowingly mak[ing] a false representation as to the characteristics . . . benefits . . . of goods or services. 78 OKLA. STAT. § 54(A)(5). Oklahoma has full authority to punish a wrongdoer by divesting that wrongdoer of profits or earnings derived from such wrongful conduct.

As for comparable criminal penalties, WLC is well aware that there are financial ramifications in the criminal context for drug companies that falsify data or conceal study data. Indeed, in 1995, WLC pled guilty to a felony conviction for intentionally concealing study data on another prescription drug and was fined $10 million for such conduct. R. 3780, Tr. 103-08. The jury's award of punitive damages in this case was right in line with WLC's knowledge of the consequences for this type of conduct.

E. The Closest and Most Analogous Case Supports the Jury Award.

In a very similar defective drug case, American Home Products (AHP) made almost identical arguments to those asserted here to the Oregon Court of Appeals when punitive damages were awarded against that company for failing to properly warn about the vision loss side effects of a prescription drug, Cordarone. *Axen v. American Home Products Corporation*, 158 Or. App. 292, 974 P.2d 224 (Or. App. 1999), *cert. denied*, 528 U.S. 1136. The evidence of reprehensibility in that case was far less compelling than the evidence here but did include evidence that AHP deliberately placed misleading information on its packaging in order to promote sales. *Id.* at 320.

As to AHP's argument that the jury's punitive award constituted an attempt by Oregon to impose its regulatory policies on the rest of the country and to punish AHP for lawful and uncharged conduct, the *Axen* Court affirmed the punitive award after going through the exact analysis articulated here by Wakefield. The court held that the company was:

> not punished for its promotional activities outside of Oregon – it was punished for failing to warn Douglas Axen's physicians that the [drug] was associated with optic neuropathy and vision loss. As a consequence of that failure to warn, Cordarone was prescribed to Douglas Axen in Oregon and was purchased and taken by him in Oregon. Douglas Axen' use of Cordarone ultimately led to his vision loss, again in Oregon. Any information submitted to the jury about [the drug company's] promotional practices was for the purpose of determining the egregiousness of [the drug company's] activities within Oregon, not as further grounds for punishment.

Axen at 240. In this case, the Oklahoma Court of Civil Appeals faced these same arguments and also affirmed the punitive award as

it "neither reflects a grossly excessive award, nor attempts to sanction Manufacturing Defendants for conduct legal in other states." Pet. App. 18.

F. The Evidence of WLC's Reprehensibility Justifies the Jury Award.

When judging the reasonableness of a punitive damages award, the court's most important indicium is the degree of reprehensibility of the wrongdoer. *BMW*, 517 U.S. at 575. Most of the factors of reprehensibility identified in *State Farm* are present in this case: (1) the harm caused was severe physical injury leading to death, rather than mere economic damage; (2) WLC's repeated misrepresentations and intentional concealment of data showed reckless disregard to public health and safety; (3) the jury heard evidence of more than two dozen incidents of wrongdoing and fraud showing a pattern of repeated actions which conduct directly caused Wakefield's death and (4) Michael Wakefield's death was the result of WLC's intentional malice and conscious deceit. *See Rhone-Poulenc Agro S.A. v. DeKalb Genetics Corp.*, 345 F.3d 1366, 1371 (Fed. Cir. 2003) *cert denied*, 540 U.S. 1183 (jury finding of intentional malice, trickery or deceit satisfies *BMW's* requirement of reprehensibility). WLC has not preserved any points of error on this issue and has accepted the jury's judgment on its conduct.

III. The Jury Award Is Not Grossly Excessive Under *State Farm* Standards.

Only when an award can "fairly be categorized as 'grossly excessive' in relation to [the state's] interests does it enter the zone of arbitrariness that violates the Due Process Clause of the Fourteenth Amendment." *BMW*, 517 U.S. at 568. This Court in *BMW* "rejected the notion that the constitutional line is marked by a simple mathematical formula," but further stated that a ratio of 10 to 1 may be relevant and appropriate. *BMW*, 517 U.S. at

582. "Single digit multipliers are more likely to comport with due process, while still achieving the State's goals of deterrence and retribution." *State Farm*, 538 U.S. at 1524. During the punitive damages stage, Wakefield's counsel suggested to the jury that it consider a range for a punitive award between $21 million (representing WLC's increased financial benefit only for the days that Wakefield took the drug) and $600 million (representing WLC's profit from sales of Rezulin). R. 3823, Tr. 3410. The actual punitive verdict was substantially below the lowest recommended range and calculated by the jury themselves at just over six times the actual damages awarded. Certainly a punitive damage award of $10 million for the tragic death of a man whose loss of wages alone were shown to be $5 million is not "grossly out of proportion to the severity of the offense." *BMW*, 517 U.S. at 576.

Further, this Court has suggested the potential propriety of maximum multipliers for punitive damages only for cases limited to economic damages. In both *State Farm* and *BMW*, the Court indicated that the economic nature of the damages was a significant factor in its decisions. *State Farm*, 538 U.S. at 1525; *BMW*, 517 U.S. at 580-81. This Court has never suggested that such maximums should apply to wrongful conduct that severely injures or kills. Certainly different limitations on punitive damages may be appropriate in cases like this, in which the defendant intentionally engaged in conduct that they knew could be fatal and actually caused a human being to die a horrible, slow and painful death. The injury involved in this wrongful death case is a far cry from the economic or mental anguish injuries involved in the cases on which WLC relies.

CONCLUSION

For the foregoing reasons, the Petition for a Writ of Certiorari should be denied.

Respectfully submitted,

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APPENDIX

APPENDIX — EXCERPT FROM WLC'S PETITION FOR CERTIORARI TO THE OKLAHOMA SUPREME COURT

* * *

IV. THE COCA AFFIRMED THE PUNITIVE DAMAGE AWARD CONTRARY TO U.S. SUPREME COURT AUTHORITY

The COCA held that, in determining punitive damages, the jury could properly consider Warner-Lambert's profits from *worldwide* sales of Rezulin, not just sales of Rezulin that caused injury in Oklahoma. Opinion at 18-20. This holding (1) squarely conflicts with U.S. Supreme Court decisions, and (2) presents important questions never determined by this Court.

In *BMW of North America v. Gore*, 517 U.S. 559, 574 (1996), the Supreme Court ruled that, under the U.S. Constitution, "the scope of the interest in punishment and deterrence that a [state] court may appropriately consider is properly limited" to the interests of that state's citizens, "rather than those of the entire Nation." *Id.* at 574. The COCA understood this to mean only that "states may not impose economic sanctions on violators of its law with the intent of changing tort-feasors' *lawful* conduct in other states," and upheld the punitive damage award because it did not "attempt[] to sanction Manufacturing Defendants for conduct *legal in other states.*" Opinion at 19-20 (emphasis added). The COCA ignored the U.S. Supreme Court's contrary holding that punitive damages may not be imposed to punish out-of-state conduct *regardless* of whether that conduct would be considered lawful or unlawful where it occurred:

> "A State cannot punish a defendant for conduct that may have been lawful where it occurred. . . .

> *Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction.*"

State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408, 421 (2003) (emphasis added). *Accord*, *Continental Trend Resources, Inc. v. OXY USA Inc.*, 101 F.3d 634, 637 (10th Cir. 1996) ("[A]ny penalty must be supported by Oklahoma's 'interest in protecting its own consumers and its own economy.' . . . [W]e read the opinion [in *Gore*] to prohibit reliance upon inhibiting unlawful conduct in other states"), *cert. denied*, 520 U.S. 1241 (1997).

The COCA decision also raises important questions not yet addressed by this Court regarding 23 O.S. Supp. 2003, § 9.1(C), which limits punitive damages to "the increased financial benefit derived by the defendant as a direct result of the conduct that caused injury to the plaintiff and other persons or entities." This Court has never adopted the COCA's position that "conduct that caused injury" includes conduct that caused injury to people outside Oklahoma, which runs afoul of the holding in *State Farm.* Indeed, given the requirement of 23 O. S. Supp. 2003, § 9.1 (C) that punitive damage awards be reduced only by punitive damage verdicts entered in *Oklahoma* courts, the adjacent statutory language referring to "injury to the plaintiff and other persons or entities" must mean injury in Oklahoma.

Moreover, by measuring "increased financial benefit" by total sales – including sales that did *not* cause any injury – the COCA ignored the restriction that punitive damages must be limited to the financial benefit "derived . . . as a direct result of the conduct that caused injury." This Court has never

adopted the COCA's position that "conduct that caused ***injury***" (emphasis added) includes conduct that did ***not*** cause any injury, such as sales of Rezulin to the vast majority of people who benefitted greatly from the drug and had no ill effects. *See In re Rezulin Prod. Liab. Lit.*, 210 F.R.D. 61, 66 n.37 (S.D.N.Y. 2002) (even plaintiffs' experts admit that "Rezulin was effective for 95 percent of the patients who ingested it"). The Constitution does not permit a punitive damage award based on "conduct that bore no relation to the [plaintiff's] harm." *State Farm*, 538 U.S. at 422.

Finally, the $10 million punitive award (seven-fold the compensatory award) is so excessive as to require this Court's exercise of its supervisory power. In *State Farm*, 538 U.S. at 425, the Supreme Court reiterated that "an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety," and stated that "[w]hen compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *See Chandler v. Denton* 1987 OK 38, ¶ 30, 741 P.2d 855, 868 ("In light of the generously and amply compensated loss for Chandler's actual harm, we find the exemplary damages allowed by the jury not to be responsive to the purpose of civil punishment."). That is exactly the case here.

* * * *